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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,927	10/22/2003	C. Norman Shealy	079069-0119	6899

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FOLEY & LARDNER LLP
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/690,927	Applicant(s) SHEALY, C. NORMAN	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,14,15 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,14-15 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendments to the claims filed 03/27/2007 have been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,4,6-10,14-15,20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantin et al. (US 5,922,764), for the reasons expressed in the previous office action dated 12/27/2006. A new rejection of new claims 20 and 22 was necessitated by amendment.

Regarding new claims 20 and 22, from the previous office action dated 12/27/2006, the composition comprises by weight 0.1-10% of the gelling agent cetylhydroxyethyl cellulose, 0.5 to 40% of an electrolyte including magnesium chloride, 20 to 99.4 % water and the composition can further comprise 0.01 to 20% of an adjuvant including glycerin, the ingredients are all within applicants claimed range. See col 3 lin 7-65, col 4 lin 53-60, col 5 lin 59-col 6 lin 6 and claims 1-7,9-10 and 18. The examiner notes the new claim language that the composition “consists essentially of” the claimed ingredients. The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. It is the position of the examiner that the active ingredients recited within Cantin would not materially affect

the basic and novel characteristics of applicants claimed invention. The recited actives in Cantin encompasses numerous agents including perfumes, pigments and surfactants, applicants actually claim perfumes, soaps and dyes in claim 10, thus by applicants own claimed invention the actives of Cantin would not materially affect the basic and novel characteristic of the claimed invention.

Applicants arguments/remarks filed 03/27/2007 have been fully considered but are not persuasive.

Applicants assert that Canton does teach the use of sodium ions in its composition and that because Canton does not necessarily teach the claimed limitation that the composition is substantially free of sodium ions, sulfate ions or both it cannot form the basis of an anticipation rejection under the theory of inherency. Applicants also assert that the examiner suggest that it is obvious to modify Canton's teaching to exclude sodium or sulfate ions in the composition.

The relevance of these assertions is unclear. While applicants are correct in that the electrolytes could be sodium ions, sulfate ions or both, the patent clearly teaches that one of the preferred electrolytes is magnesium chloride, which can be used alone, therefore there is a clear teaching that the compositions of Canton can contain only one electrolyte which can preferably be selected as magnesium chloride. Since it is inherent from the teachings of Canton that magnesium chloride can be selected as the only electrolyte in the composition, Canton meets the limitation that the composition is substantially free of sodium ions, sulfate ions or both. Contrary to applicants assertion the examiner did not suggest it would be obvious to modify the composition of Canton,

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the basic and novel characteristics of applicants claimed invention. The recited actives in Cantin encompasses numerous agents including perfumes, pigments and surfactants, applicants actually claim perfumes, soaps and dyes in claim 10, thus by applicants own claimed invention the actives of Cantin would not materially affect the basic and novel characteristic of the claimed invention.

Applicants arguments/remarks filed 03/27/2007 have been fully considered but are not persuasive.

Applicants assert that Canton does teach the use of sodium ions in its composition and that because Canton does not necessarily teach the claimed limitation that the composition is substantially free of sodium ions, sulfate ions or both it cannot form the basis of an anticipation rejection under the theory of inherency. Applicants also assert that the examiner suggest that it is obvious to modify Canton's teaching to exclude sodium or sulfate ions in the composition.

The relevance of these assertions is unclear. While applicants are correct in that the electrolytes could be sodium ions, sulfate ions or both, the patent clearly teaches that one of the preferred electrolytes is magnesium chloride, which can be used alone, therefore there is a clear teaching that the compositions of Canton can contain only one electrolyte which can preferably be selected as magnesium chloride. Since it is inherent from the teachings of Canton that magnesium chloride can be selected as the only electrolyte in the composition, Canton meets the limitation that the composition is substantially free of sodium ions, sulfate ions or both. Contrary to applicants assertion the examiner did not suggest it would be obvious to modify the composition of Canton,

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firstly obviousness is not a valid argument for a **35 USC § 102** rejection. There is no reason to modify the composition of Canton because the patent teaches the same composition currently claimed by applicants, as described in the previous office action and above.

Applicants assert that Cantons compositions do not inherently possess the same properties as the compositions recited in the amended claims. Applicants also asserts unexpected results that were discovered in which certain ions interfere with the ability of magnesium-containing compositions to increase serum DHEA levels.

As detailed in the previous office action dated 12/27/2006 the limitation that the method of applying the magnesium containing composition lowers DHEA levels in an individual is met by Cantin, it is the position of the examiner that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In the instant case applicants are claiming a new use, property or function of a composition already known in the prior art and is therefore applicants claimed invention is not patentably distinct from the Cantin reference. Also see *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Regarding applicants argument of unexpected results, Evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35

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U.S.C. 102 rejections and thus cannot overcome a rejection so based. In re Wiggins, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-11,14-15 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantin et al. (US 5,922,764) in view of Alban et al. (US 5,420,118), for the reasons set forth in the office action dated 12/27/2006. A new rejection of new claims 20-22 was necessitated by amendment.

Regarding new claims 18 and 19, it is obvious from the disclosure of Cantin that the electrolytes used in the composition ($MgCl_2$) were used to reduce irritation caused by the active ingredient, which is caused by a lack of electrolytes such as magnesium at the site of application. See col 1 lin 26-35. It would therefore be obvious to one with skill in the art to measure the level of magnesium in an individual in order to determine through routine experimentation the effective amount of electrolyte that should be applied in combination with the active in order to optimize the amount of electrolyte used to reduce irritation by the active and applying that optimized composition to the individual in need.

Applicants arguments/remarks filed 03/27/2007 have been fully considered but are not persuasive.

Applicants assert that Alban neither discloses or suggests the compositions can be substantially free of sodium ions, sulfate ions or both and provides no motivation to exclude those ions.

The relevance of this assertion is unclear. Alban was used primarily for its disclosure on the use of methylcellulose in skin care compositions, and since Alban is used only as a secondary reference in combination with the main reference (Cantin) it does not have to disclose all of applicants claimed invention on its own merit. As disclosed in the previous office action it would have been obvious to combine Cantin and Alban, by combination the references disclose all of applicants claimed invention.

Applicants assert that new claims 18 and 19 are patentable over Cantin and Alban.

The examiner disagrees with this assertion because the new limitation would be obvious in view of Cantin; see the above remarks.

Lastly applicants state that claims 20-22 are patentable over Cantin and Alban because of the new transitional phrase "consisting essentially of" would preclude the actives of Cantin.

The examiner as detailed above in this action disagrees with this assertion, the actives disclosed within Cantin are not precluded by applicants new transitional phrase.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Michael G. Hartley", with a stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER